TMJ

Patient Matched Joint Replacement

BIOMET® MICROFIXATION

Anticipate. Innovate.™

Product Overview

Anticipation and innovation. These two qualities have made Biomet Microfixation an industry leader. Founded by Walter Lorenz more than thirty years ago, Biomet Microfixation offers instrumentation, plating systems and related products for a wide range of surgical procedures.

Biomet Microfixation incorporates Biomet's 30 years of Orthopedic total joint experience into the design and materials utilized in both TMJ Replacement Systems.

Stock Design

Biomet Microfixations's Stock TMJ replacement system has been manufactured and clinically used since July 1995 under an approved investigational device exemption (IDE) from the FDA. In this 10 year IDE study, our stock prosthesis proved to be compatible for 88% of patients. Today, over 2,500 implants have been implanted worldwide.

Patient Matched Design

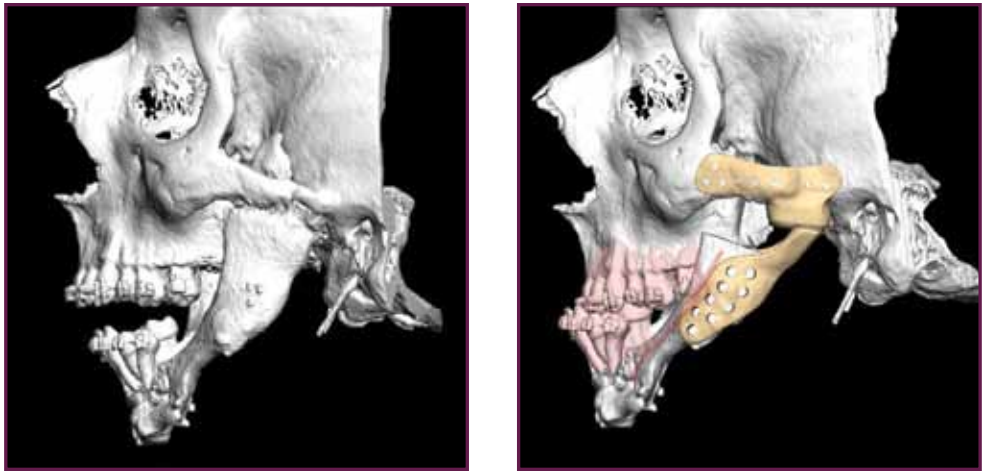
In today's TMJ market , traumatic reconstructive cases or extreme anatomical variations may require the development of a patient matched implant. Combining the precision of patient specific positioning guides developed from an MRI with the latest web technology allows for a state-of-the-art, custom fit implant.

PMI is Ideal for Patients:

- Missing a large part of ramus and/or mandible
- With a very thin zygomatic arch
- Needing simultaneous orthognathic reconstruction

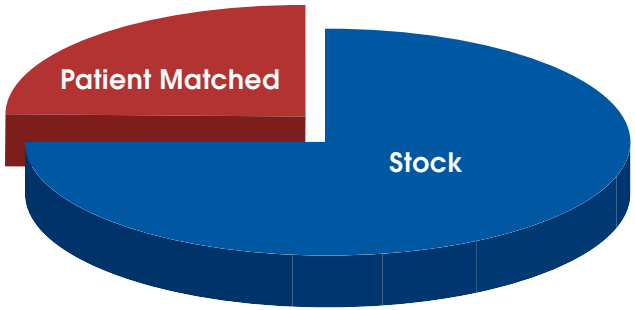
"Alloplastic TMJ reconstruction will make a difference for the patient ."

-Dr. Esben Aagaard



Patient missing large part of mandible requiring extensive changes to the mandible and fossa components.

Stock vs. Patient Matched Cases



For those rare, complex cases Biomet's Patient Matched Implant is your solution

Impacting Lives

Surgeon Testimonials

"The resulting fit and post operative outcomes of Biomet's Patient Matched Implants in patients with complex anatomic deformities or simultaneous occlusal corrections have been very gratifying. It has helped make a significant and predictable difference in patients with severely challenging problems."

- Dr. David Psutka, Senior Staff Surgeon, Mount Sinai Hospital, Toronto, Canada

"The Biomet Microfixation Total Joint Prosthesis has proven to be a superb device in 9 years of use in our program. The opportunity to now offer a custom "Patient Matched" prosthesis for complex reconstructions, to be directly involved in the design process using internet technology and to be assured of a precise fit is very exciting; all to the benefit of our special patient population."

-Dr. Gerald Baker, Head of OMS Division , Mount Sinai Hospital, Toronto, Canada"

Being a part of the design process is not only exciting but it gives me more confidence that my surgery will go very smoothly and precisely."

-Dr. Esben Aagaard

Patient Testimonials

"One surgeon told me there was not anything I could do for my jaw problems. But I couldn't open my mouth and was in serious pain. With a second opinion and Biomet's Patient Matched Implants, I finally found my solution."

"I have my life back after having Biomet's Patient matched Implants. I can now enjoy actual meals again. More importantly, my husband and children have their wife and mom back!"

- Lori Murphy, Toronto, Canada

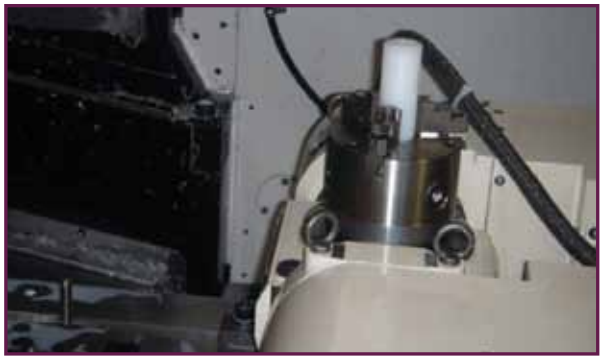
"Biomet's Patient Matched Implant gave me a new beginning. Now I can plan my future without pain in my daily life!"

"With the great results from my Biomet Patient Matched Implants, I'm left (lightheartedly) asking my surgeon, 'Why didn't we do this replacement procedure 20 years ago?"

BIOMET®
MICROFIXATION
Anticipate. Innovate.™

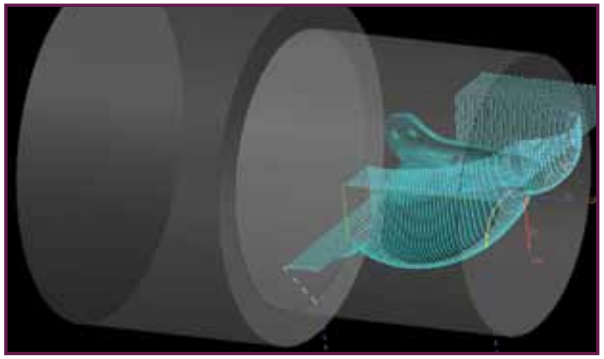
Innovative manufacturing Process

Patient Matched Fossa



Step 1.

Using our state-of-the-art, 5-Axis robotic machine, raw material is cut to the precise size and length.



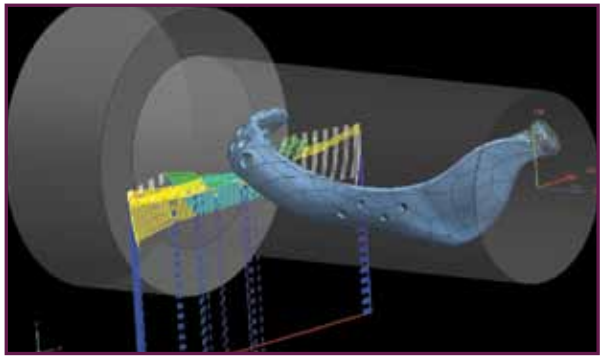
Step 2.

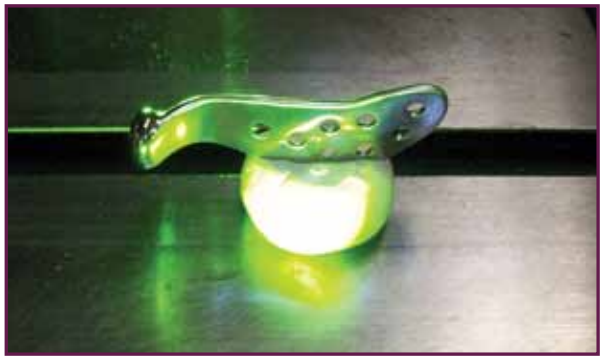
Using computerized numeric control programming, our 5-Axis machine mills the patient specific contour of the fossa socket and flange.

Step 3.

Once the fossa component is produced, a meticulous inspection of the articulating surface and the anatomical compatibility is performed.

Patient Matched Mandibular



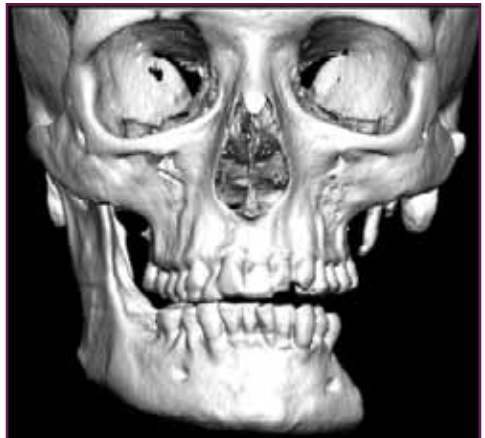


Development Process

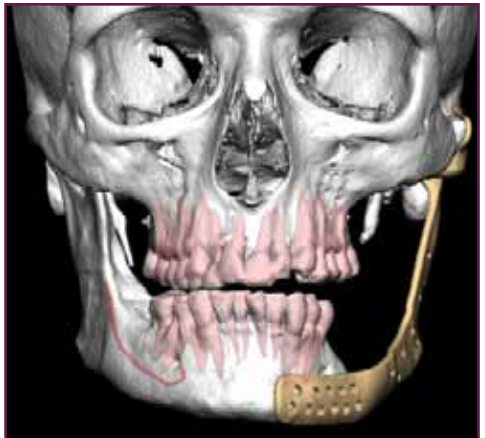
Typical Development Timeline

Send CT Scan	Week 1
Web Conferencing and Surgical Planning	Week 2
Implant Approval	Week 3
Impant Manufactured	Week 4
Surgery	Week 5

*This timeframe will vary based on surgeon response time.

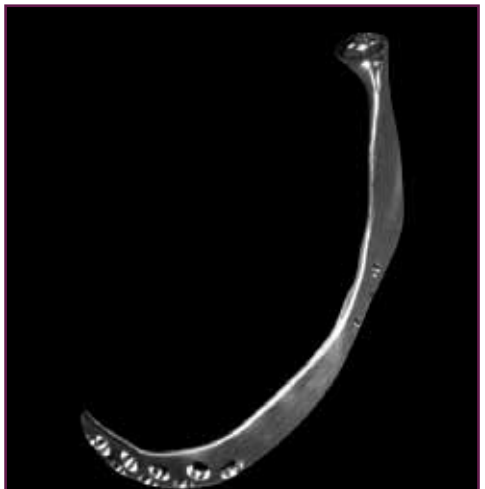


CT of patient skull



CT of skull with a customized implant model

CT of customized implant model



Customized TMJ implant

Patient Matched Capabilities

Surgical Planning via Web Conference

- Reduces development time
- Interactive forum with direct anatomical and implant visualization
- Final implant design is verified

Operative Guides

- Burring Guides
- Cutting Guides
- Implant Placement Guides

Bite Splints

- Ensures proper occlusion when simultaneously performing orthognathic adjustments
- Dental impressions are needed

Screw Length Charts

- Illustrates depth of bone
- Provides screw length recommendations
- States the distance from top of condylar head to skull base for post-operative referencing on CT scan.

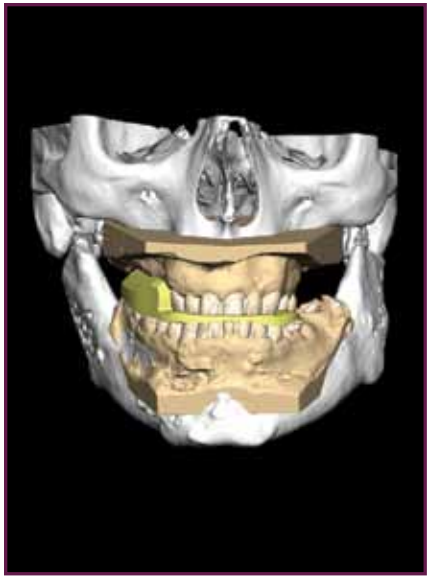
ClearView® Model: Intra-Operative Reference

- Shows location of nerves
- Shows outline of proper placement for the implant

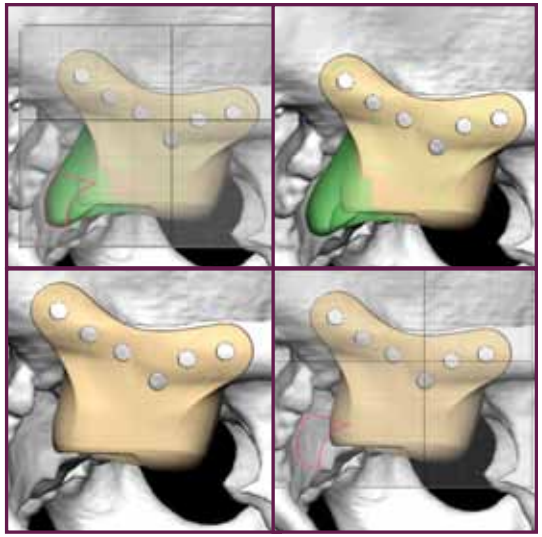
Fossa Design Options

- Anterior and posterior lip capabilities to prevent dislocation or condylar shifting

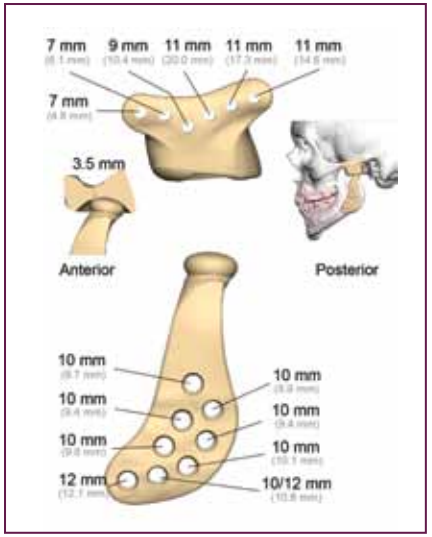
Burring Guides



Bite Splint

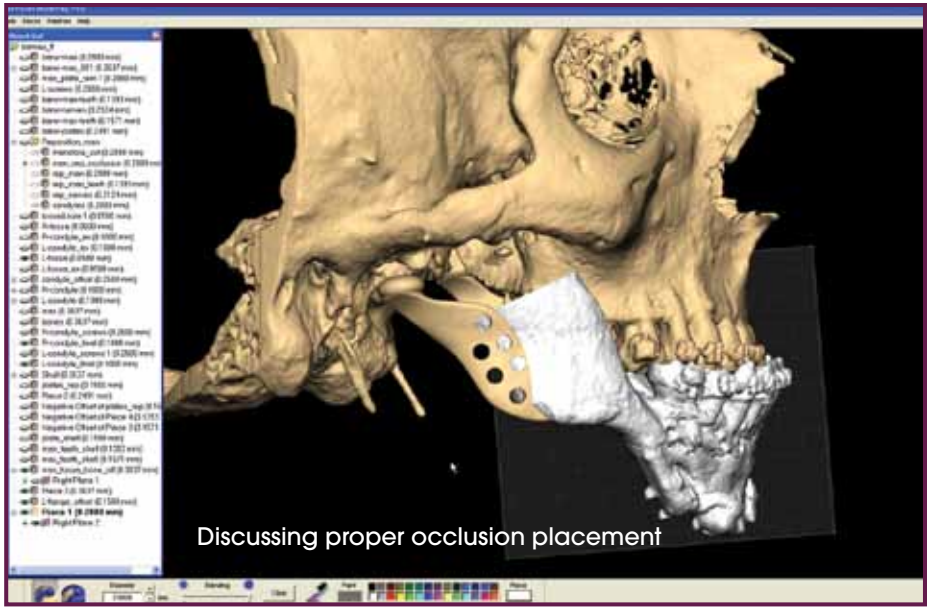


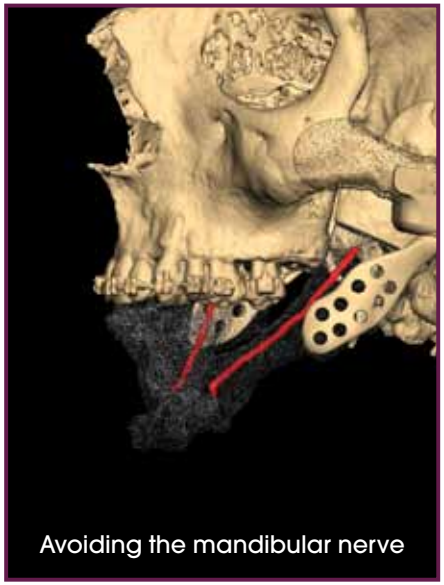
Posterior Fossa Lip Option

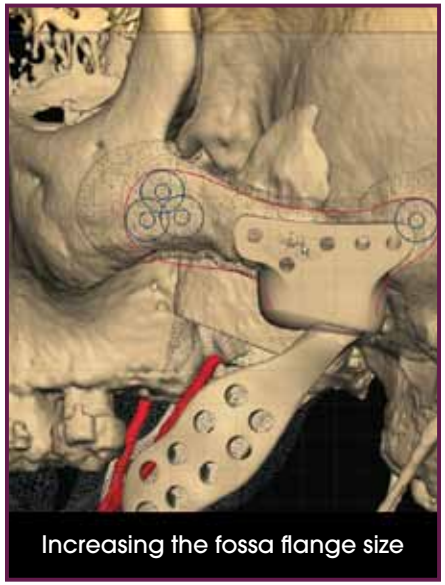


Screw Length Chart

Web Conference Feature


Discussing proper occlusion placement


Avoiding the mandibular nerve


Increasing the fossa flange size

Web Conference Call

- Significantly reduces the total time needed to complete the project
- Provides an interactive forum with direct anatomical and implant visualization
- Allows for surgeon and engineer discussions and dual maneuvering capabilities
- Surgeon shows precisemodifications or adjustments ofthe implant and verifies the final design

Surgeon Designed. Patient Matched.

Using the Biomet Patient Matched TMJ prosthesis gives me the opportunity to work with the designing engineers via an innovative web conference, providing direct input into each implant's design."

- Dr. David Psutka, Senior Staff Surgeon, Mount Sinai Hospital, Toronto, Canada

Ordering Information

If you are interested in utilizing Biomet Microfixation's Patient Matched Implant program, please send in the following forms:

- **Patient CT Scan Protocol**
- **Design Input Form**
- **Prescription Form for Custom Products**

Custom TMJ Design Input Questionnnaire Form

Custom TMJ CT Scanning Protocol Form

Send forms electronically or fax to Medical Modeling

Email: info@medicalmodeling.com

Phone: 888.273.5344 • Fax: 303.273.6463

Contact Biomet Microfixation for online CT Data Uploading Instructions or visit www.medicalmodeling.com.

Caution

Federal Law (USA) restricts this device to sale, distribution, or use, by or on the order of a physician.

Description

The Total Temporomandibular Joint (TMJ) Replacement System is implanted in the jaw to functionally reconstruct a diseased and/or damaged temporomandibular joint.

The Total TMJ Replacement System is a two-component system comprised of mandibular condyle and glenoid fossa components.

Both components are available in multiple sizes as right and left side specific designs and are attached to the bone by screws. Included in the system are trials, instruments and instrument cases.

Materials

- Mandibular Component—Cobalt-Chromium-Molybdenum (Co-Cr-Mo) alloy with titanium alloy coating or Titanium (Ti-6Al-4V) alloy with titanium alloy coating
- Fossa Component—ultra high molecular weight polyethylene (UHMWPE)
- Screws—titanium alloy
- Trials: Mandibular—aluminum, Fossa—Radel® plastic
- Instruments: TMJ flat diamond rasp, TMJ diamond burrs, TMJ double-ended drill guide, retractors—stainless steel
- Instrument Case—stainless steel, silicone, Radel® plastic

Indications

The Total Temporomandibular Joint Replacement System is indicated for reconstruction of the temporomandibular joint. The reconstruction is necessary due to one of the following diagnoses:

- Arthritic conditions: osteoarthritis, traumatic arthritis, rheumatoid arthritis
- Ankylosis including but not limited to recurrent ankylosis with excessive heterotopic bone formation
- Revision procedures where other treatments have failed (e.g. alloplastic reconstruction, autogenous grafts)
- Avascular necrosis
- Multiply operated joints • Fracture • Functional deformity • Benign neoplasms
- Malignancy (e.g. post-tumor excision) • Degenerated or resorbed joints with severe anatomic discrepancies • Developmental abnormality

Contraindications

- Active or chronic infection.

Warnings and Precautions for Use of the Total TMJ Replacement

Contraindications

• Active or chronic infection.
• Patient conditions where there is insufficient quantity or quality of bone to support the components.
• DO NOT USE the individual components of this total system (e.g. mandibular components, fossa components, or screws) for partial joint reconstruction.
• Bone cement or other grouting agents should not be used when implanting these devices. Safety and efficacy have not been established for the use of bone cement or other grouting agents with these implants.
• DO NOT USE IN CHILDREN. The Total TMJ Replacement was designed for skeletally mature patients.

Precautions

The device is limited to surgeons who are adequately trained in the use of the device through hands-on and educational course work. In all cases sound medical practice is to be followed and the surgeon must select the type of device appropriate for treatment. The patient is to be warned that the system does not replace normal healthy bone in their TMJ and they may continue to have chronic pain and limited range of motion. The system can break or loosen as a result of stress, activity, or trauma. Patients with severe hyper-functional habits may have an undesirable outcome. The presence of existing mandibular and/or zygomatic arch screws or screw holes may compromise fixation. Note that placement of the implant in one joint only may result in harmful effects to the joint on the opposite side. Placement of the implant may produce an improper relationship between teeth surfaces that should contact during biting. The patient is to be made aware of surgical risks and possible adverse effects prior to surgery and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

Specialized instruments/trials are designed for use with the Total TMJ Replacement System to aid in the accurate implantation of the components. DO NOT USE trials/instruments or cases that are disfigured, cracked, corroded, or otherwise damaged. Instruments/trials are subject to wear with normal usage and are susceptible to fracture when exposed to extensive use or excessive force. All trials/instruments and cases should be regularly inspected for wear or disfigurement. These should be disposed of appropriately.

Adverse Events

Adverse events that may occur following placement of the Total TMJ Replacement System are listed below. See Tables 7 and 8 located in the insert # 01-50-1000 for more detailed information on adverse events from the clinical trial.

• Removal of components(s) including, but not limited to the following: - implant changes caused by loading and/or wear - degenerative changes within the joint surfaces from disease
or previous implants - implant materials producing particles or corroding
• Loosening or displacement with or without removal of the implant • Infection (systemic or superficial) • Foreign body or allergic reaction to implant components • Fossa wear through
• Facial swelling and/or pain • Facial nerve dysfunction • Excision of tissue • Heterotopic bone formation • Neuroma formation
• Ear problems • Dislocation

Patient Counseling Information

• Discussion of the following points is recommended prior to surgery.
• The importance of prompt medical attention if they experience unusual swelling in the area of the implant.
• The risks associated with a Total TMJ System (see Warnings and Adverse Events).
• Post-operative pain relief and return of function varies from patient to patient.
• Additional treatment may be required including but not limited to extended physical therapy, bite splint, dental braces, and/or orthognathic and reconstructive surgery.

Sterility

The Total Temporomandibular Joint Replacement System mandibular and fossa components are sterilized by exposure to a minimum of 25 kGy of gamma irradiation. DO NOT RESTERILIZE. Screws, trials, and the TMJ Instrument Case containing instruments are supplied non-sterile and should be wrapped with an FDA cleared sterilization wrap prior to steam sterilization in order to maintain sterility.

What fascinates you about the body is also what drives us. That's why we're always pushing the boundaries of engineering to make products that help you keep the human form as glorious as it was intended. To learn more about our breadth of products, call 800-874-7711 or visit us online at biometmicrofixation.com. We'd love to join you in a conversation about the future.

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For more information on the OnPoint™ 1.2mm Scope System or other related TMJ products, please contact us at:

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